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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,975	09/24/2003	Brian Penick	10553-2802CIP	4875
31292 7590 03/26/2007 CHRISTOPHER & WEISBERG, P.A. 200 EAST LAS OLAS BOULEVARD SUITE 2040 FORT LAUDERDALE, FL 33301			EXAMINER KANTAMNENI, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/669,975	Applicant(s) PENICK, BRIAN	
	Examiner Shobha Kantamneni	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-34 are pending in this application.

Election/Restrictions

Claims 26-34 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election without traverse of invention Group I, directed to a topical composition for treatment of skin conditions comprising sulfur, selenium sulfide and a carrier vehicle wherein a weight percent of the sulfur in the topical composition is at least equal to or greater than weight percent of the carrier, claims 1-25 in reply filed on 12/27/2006 is herein acknowledged. The restriction requirement is herein made final.

Claims 1-25 are examined herein on the merits as they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "carrier vehicle" in independent claims 1, 4, and 6 renders the claims vague and indefinite, as it is not clear what other compounds this

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recitation encompasses, and since one of ordinary skill in the art could not ascertain the metes and bounds as to "carrier vehicle". The specification on page 4, paragraph [0015] merely recites that "the carrier vehicle includes, but is not limited to, VASELINE, petroleum jelly, or lard". However, one of ordinary skill in the art could not ascertain and interpret the metes and bounds as to "carrier vehicle", since one of ordinary skill in the art would clearly recognize many, various, and possible carrier vehicles such as aqueous, non-aqueous, organic, inorganic carrier vehicles such as water, alcohols, silicates, gums, waxes etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 13-19, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (US 5,716,606, PTO-892), in view of Peffly et al. (US 7,001,594, PTO-892).

Boyce et al. disclose a lotion based topical composition comprising sublimed sulfur preparation for treatment of dermatitic skin disorders and keloids in particular. See abstract; column 2, lines 28-32. The composition contains 50 % by weight sulfur with a spreadable carrier. See Table 1, column 2. It is also disclosed that sulfur has germicidal, fungicidal, and keratolytic activity. See

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column 1, lines 10-14. It is also taught that other spreadable carrier bases, such as gels, salves, creams, other lotions, ointments, soaps, oils, and dusting powders may be used to carry the high concentration of sulfur to the dermatitic condition. See column 2, lines 46-50.

Boyce et al. do not teach the employment of selenium sulfide, ketoconazole, pyrrithione zinc, in the composition therein.

Peffly et al. teach topical cosmetic compositions for treatment of dermatitic conditions comprising antifungal active agents such as pyrrithione salts, ketoconazole, sulfur or sulfur-containing actives such as selenium sulfide. The preferred concentration of zinc pyrrithione is from about 0.005 % to 2 %; selenium sulfide is from about 0.001 % to about 2.5 %. See column 4, lines 51-62.

It would have been obvious to a person of ordinary skill in the art at the time of invention to add antifungal agents zinc pyrrithione, ketoconazole, and selenium sulfide to the composition of Boyce et al.

It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Borce et al. and Peffly et al. the instant claims contain antifungal agents sulfur, zinc pyrrithione, ketoconazole, and selenium sulfide *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

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Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (US 5,716,606, PTO-892), in view of Peffly et al. (US 7,001,594, PTO-892).

Boyce et al., and Peffly et al. are as discussed above.

The combination of references do not teach the specific amounts of zinc pyrithione, ketoconazole, and selenium sulfide.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as amounts of zinc pyrithione, ketoconazole, and selenium sulfide in the skin care composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the amounts of pyrithione, ketoconazole, and selenium sulfide employed in the compositions, since the optimization of amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in cosmetic science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (US 5,716,606, PTO-892), in view of Peffly et al. (US 7,001,594, PTO-892) as applied to claims 1-7, 9, 13-19, and 24 above, in view of Giovanni et al. (EP 0242553, PTO-892).

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Boyce et al., and Peffly et al. are as discussed above.

The references do not teach the instant percent of sulfur in the composition.

Giovanni et al. discloses topical pharmaceutical composition containing 99.5 % sulfur and 0.5 % allantoin in a powder form (example 1). Example 18 discloses the composition in a gel or paste form. Giovanni et al. further teaches that the amount of sulfur in a topical composition may be up to 99.5 % and the amount of the carrier to sulfur ratio depends on the pharmaceutical form. See Page 2, lines 20-22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the amount of sulfur in the composition with the expectation of similar results, since Giovanni discloses that a high amount of sulfur may be incorporated into a topical composition and the ratio of sulfur to carrier depends on desired pharmaceutical form, i.e. gel cream, or powder.

Claims 10-12, and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (US 5,716,606, PTO-892), in view of Peffly et al. (US 7,001,594, PTO-892) as applied to claims 1-7, 9, 13-19, and 24 above, in view of Earles (US 5632975, PTO-892).

Boyce et al., and Peffly et al. are as discussed above.

The combination of references do not specifically teach a non-aqueous composition.

Earles teaches a composition containing sulfur for treating seborrheic dermatitis. Earles discloses that a hydrocarbon base allows the composition to

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retain moisture in the skin and aids in the penetration of the sulfur. See column 3, lines 59-61.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a hydrocarbon carrier-base, since Earles teaches that hydrocarbon carrier-base allows the skin to retain its moisture and enhance penetration of sulfur. One would have been motivated to employ hydrocarbon bases such as VASELINE, petroleum jelly or lard with the expectation of similar results in Boyce's composition, since Boyce teaches that the carrier base is selected according to desired consistency, feel, and look and most carriers are suitable.

Conclusion

No claims are allowed.

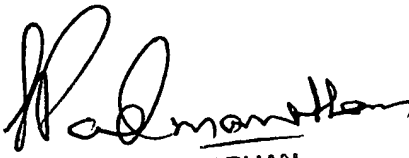
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER